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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/726,193	11/29/2000	Chih-Ming Chen	300.1023	6199

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EXAMINER	
FUBARA, BLESSING M	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 07/15/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/726,193	CHENG ET AL.	
	Examiner	Art Unit	
	Blessing M. Fubara	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *paper nos.8 & 10* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20 and 24-34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20 and 24-34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *4 & 9* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Examiner acknowledges receipt of extension of time and amendment A filed 04/11/02, and IDS and amendment B filed 04/26/02. Claims 1-20 and 24-34 are pending.

Claim Rejections - 35 USC § 102

1. Rejection of claims 1-29 under 35 U.S.C. 102(b) as being anticipated by Physician Desk Reference (PDR) on Glucophage (50th edition, pages 752-757) is withdrawn.

2. Rejection of claims 1-29 under 35 U.S.C. 102(e) as being anticipated by Moeckel et al. (US 5,955,106) is withdrawn.

Claim Rejections - 35 USC § 103

3. Claims 1-20 and 24-34 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Bhagwat et al. (US 6,056,977).

Upon further consideration, applicants' arguments presented in the interview of 03/21/02 is not persuasive. Applicants have agued that Bhagwat teaches hypoglycemic drug and that hypoglycemic drug is not an antihyperglycemic drug. Applicants in the interview of 03/21/02 stressed that the drug formulation of the application releases the antihyperglycemic drug over a period of 12-24 hours.

In response to the argument that hypoglycemic drug is not antihyperglycemic is not persuasive because hypoglycemic drug does the same function as antihyperglycemic drug. Bhagwat specifically lists metformin as hypoglycemic drug and metformin is an antihyperglycemic drug as acknowledged and claimed by applicants. Bhagwat discloses that metformin, butformin, glipzide and phenformin are formulated as controlled release dosage forms. The argument that the formulation of the instant application releases the

antihyperglycemic drug over a period of 12-24 hours is not persuasive because the application broadly claims pharmaceutical composition comprising an antihyperglycemic drug or a pharmaceutically acceptable salt thereof. Intended use is not critical in a composition claim. In the absence of a showing of unexpected result, once a day dosing or release of the active agent over a period of 12-24 hours is not inventive over the prior art. There is nothing in the composition that differs from the prior art that affords the composition of the application the property claimed and there is no showing that the composition of the prior art would not have that property. If there is one, applicants have not presented the difference. It is not enough to say that a composition comprising A, B and C releases C over a period of 12-24 hours, and another composition comprising A, B and (C or D or E or F) would not release C over a period of 12-24 hours. What is the criticality of the 12-24 hours of the application over the formulation of the prior art?

Since applicants did not address merits of demerits of the rejection on record in the response filed on 04/11/02 and 04/26/02, a summary of the rejection is given below.

Bhagwat et al. discloses a controlled release pharmaceutical coated tablet formulation wherein the formulation comprises the hypoglycemic drug, glipizide, surfactants, excipients, diluents, hydroxymethylcellulose, hydroxypropyl methylcellulose phthalate, methacrylic acid ester copolymers, suitable plasticizer, sorbitol, sodium chloride enhancer, ethylenediamine and polyvinylpyrrolidone. See abstract, column 4, lines 27-54, column 6, lines 20-67, column 7, line 66 to column 8 and line 60, column 9, line 63 to column 10 and line 33, column 11, lines 30-41, column 12, lines 22-47, examples 4, 5, 7 and 8 and claims 1-16. The amounts of diluent in the formulation ranges from 5% to about 50% by weight of the total dosage unit (column 8, line 66).

Bhagwat et al. teaches that hypoglycemic drugs such as metformin, buformin, glipizide and phenformin are formulated as controlled release microspheres, and that art known extended release glipizide dosage forms are prepared as osmotic device wherein the core is surrounded by a semipermeable membrane that has laser-drilled orifice (column 3, lines 8-47). The expected result is a controlled release pharmaceutical tablet formulation comprising hypoglycemic agent, semipermeable membrane having an orifice/aperture and surrounding a core, plasticizers, enhancers, diluents, carriers and binders such as polyvinylpyrrolidone. The instant claims are broad and when and how the composition is administered is not critical to a composition claim. The influence of food intake on the bioavailability of the drug is not critical in a composition claim. The claims are directed to a composition comprising antihyperglycemic drug or a pharmaceutically acceptable salt and the agent is metformin. Bhagwat suggests metformin controlled release formulation.

Therefore, it is prima facie obvious to one of ordinary skill in the art at the time the invention was made to use the teachings of Bhagwat et al. One having ordinary skill in the art would have been motivated to prepare a controlled release dosage tablet wherein the dosage tablet comprises glipizide hypoglycemic agent, apertured semipermeable membrane surrounding a core, surfactants, excipients, diluents, hydroxymethylcellulose, hydroxypropyl methylcellulose phthalate, methacrylic acid ester copolymers, suitable plasticizer, sorbitol, sodium chloride enhancer, ethylenediamine and polyvinylpyrrolidone. In the absence of a showing of unexpected result, the application is not inventive over the prior art.

Double Patenting

Examiner agreed to reconsider arguments presented against the obviousness type double patenting issues raised in the last office action. Examiner has reconsidered the issue and maintains the rejection. Applicants, however, in the response filed 04/11/02 and 04/26/02 did not present any arguments except that the specification of the copending application was relied upon in the rejection. This is not the case and since a formal argument was not presented, the rejection is summarized below.

4. Claims 1-20 and 24-34 remain rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-29 of U.S. Patent Nos. 6,099,859. Although the conflicting claims are not identical, they are not patentably distinct from each other because the application is directed to composition comprising antihyperglycemic drug and the claims of the issued patent teach composition comprising antihyperglycemic agent. The difference is that the patent teaches 50-98% antihyperglycemic drug.

5. Claims 1-20 and 24-34 remain provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim1-54 of copending Application No. 09/594,637. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of both applications are directed to antihyperglycemic drugs.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

7. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicants' cooperation is requested in correcting any errors of which applicants may become aware in the specification.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is 703-308-8374. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3592 for regular communications and 703-305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

Blessing Fubara
July 12, 2002

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600